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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,893	04/06/2001	Kjell Olmarker	003300-765	3406

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	16

DATE MAILED: 11/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/826,893	OLMARKER ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18,20-23 and 25-28* is/are pending in the application.

4a) Of the above claim(s) *20-23 and 25-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16,18,20-23 and 25-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,10,13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-16, 18, 20-23 and 25-28 are pending in the instant application. Claims 1, 18, 20 and 25 have been amended and claims 17, 19, 24 and 29 have been canceled as requested by Applicant in Paper Number 15, filed Sept. 19, 2002, 2002.

Election/Restrictions

2. Applicant's election with traverse of Group I in Paper No. 15 is acknowledged. The traversal is on the ground(s) that: the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden." Additionally, the Applicants assert that the particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated, and that a mere statement of conclusion is inadequate. Applicants further submit that a serious burden to examine both groups of claims has not been adduced, that a search of the method of treating and the compositions used in the methods would result in an overlapping search of the claims of Group II, and additionally the added species requirement further limits any search burden.

Applicants' arguments have been fully considered but are not deemed persuasive.

Consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof: (B) a separate status in the art when they are classifiable together: (C) a different field of search:. Groups I and II have a separate status in the art because

Group I is drawn to a method of treatment and Group II is drawn to pharmaceutical compositions, which have a separate status in the art. Inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case TNF-α inhibitors can be used to treat diseases or disorders other than nerve disorders. Further, a search is directed not only to art which would be anticipatory, but also to art that would render the invention obvious.

The requirement is still deemed proper and is therefore made FINAL.

Species Election

3. Applicant's election with traverse of the TNF-α inhibitor CDP-870, and nerve root injury, in Paper No. 15 is acknowledged. The traversal is on the ground(s) that: no basis as to why a search of these categories would be burdensome, let alone seriously burdensome, was set forth in the Office Action as required.

Applicants' arguments have been fully considered and deemed persuasive for the species elections, therefore, the requirement for species election is withdrawn.

Claims 20-23 and 25-28 are withdrawn as being drawn to a non-elected invention.

Claims 1-16 and 18 are currently under examination.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor (specifically Bjorn Rydevik).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5.1 Claims 1-16 and 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-18 of copending Application No. 09/760,810, and claims 35-51 of copending Application 09/743,852. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass methods of treating nerve disorders or injuries by administration of compounds that inhibit the activity of TNF-α.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5.2 Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 6-10 of copending Application No. 09/760,811. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass methods of treating sciatica by administration of a compound that inhibit the activity of TNF-α.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The effective priority date of the instant application is the filing date, April 6, 2001, since the claims are limited to a method of treatment with CDP-870, and this method was not disclosed in any of the priority documents.

Claims 1-16 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Tobinick, US Patent No. 6,419,944, filing date April 5, 2001. Claims 1-16 and 18 encompass a method for

inhibiting the action of TNF-α for treating nerve disorders in a subject, which may be vertebrate, mammal or human, comprising administering the TNF-α inhibitor CDP-870, wherein the nerve disorder is a spinal disorder (which may be spinal cord compression), nerve root injury, sciatica, caused by herniated discs, involves pain, is nucleus pulposus-induced nerve injury, and wherein the TNF-α inhibitor is administered systemically, locally, parenterally, intramuscularly, intravenously by injection or infusion, subcutaneously, orally at a dosage of about 20 mg to about 1,500 mg, rectally, or administered at a dosage of about 1 mg/kg to about 50 mg/kg body weight of said subject.

Tobinick teaches that antagonists to tumor necrosis factor can be used to treat nerve disorders in humans, which may be due to a herniated nucleus pulposus, including damage to the spinal cord (compression), nerve roots, herniated discs and sciatica, and that one such antagonist which may be used is CDP 870, (see entire patent and claims, especially column 2, line 1 to column 3, line 20, column 5, lines 58-65, and claims 21, 33 and 35). Tobinick also teaches that the antagonist may be administered locally (subcutanteosly, column 5, lines 8-15), and the dosage can be between 1 and 300 mg (see column 10, line 29 to column 11, line 5 and claim 12). Therefore, Tobinick anticipates the claims.

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

LORRAINE SPECTOR
PRIMARY EXAMINER